

PEPPER HAMILTON, LLP

301 Carnegie Center
Suite 400
Princeton, NJ 08543-5276
(609) 452-0808

Attorneys for Plaintiffs

*DOW PHARMACEUTICAL SCIENCES, INC. and
VALEANT PHARMACEUTICALS NORTH AMERICA LLC*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

DOW PHARMACEUTICAL SCIENCES,)
INC. and VALEANT PHARMACEUTICALS)
NORTH AMERICA LLC,)
Plaintiffs,) Civil Action No.:
v.)
PERRIGO COMPANY and)
PERRIGO ISRAEL PHARMACEUTICALS)
LTD.,)
Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Dow Pharmaceutical Sciences, Inc. (“Dow”) and Valeant Pharmaceuticals North America LLC (“Valeant”) (collectively “Plaintiffs”) by way of Complaint against Defendants Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”) (collectively “Defendants”) allege as follows:

THE PARTIES

1. Dow is a corporation organized and existing under the laws of California having its principal place of business at 1330 Redwood Way, Petaluma, CA 94954.

2. Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 700 Route 202/206 N, Bridgewater, NJ 08807.

3. Upon information and belief, Perrigo Company is a Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

4. Upon information and belief, Perrigo Israel is an Israeli corporation with its principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel. Upon information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo Company.

NATURE OF THE ACTION

5. This is an action for infringement of United States Patent No. 8,288,434 ("the '434 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Perrigo Israel's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%, for topical use ("Perrigo's generic clindamycin phosphate and benzoyl peroxide gel").

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, this Court has jurisdiction over Perrigo Company. Upon information and belief, Perrigo Company is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products manufactured by Perrigo Israel. Upon information and belief, Perrigo Company directly, or indirectly, manufactures, markets and sells generic drug products throughout the United States

and in this judicial district. Upon information and belief, Perrigo Company purposefully has conducted and continues to conduct business in this judicial district.

8. Upon information and belief, this court has jurisdiction over Perrigo Israel. Upon information and belief, Perrigo Israel directly, or indirectly, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Perrigo's generic clindamycin phosphate and benzoyl peroxide gel. Upon information and belief, Perrigo Israel purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

COUNT FOR PATENT INFRINGEMENT

10. The U.S. Patent and Trademark Office ("PTO") issued the '434 patent on October 16, 2012, and the '434 patent expires on August 5, 2029. The '434 patent claims, *inter alia*, formulations of benzoyl peroxide, including formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the '434 patent and have the right to sue for infringement thereof. A copy of the '434 patent is attached hereto as Exhibit A.

11. Dow is the holder of New Drug Application ("NDA") No. 050819 for Acanya®, which the FDA approved on October 23, 2008. In conjunction with NDA No. 050819, the '434 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

12. Clindamycin phosphate and benzoyl peroxide gel, 1.2%/2.5%, is sold in the United States under the trademark Acanya®.

13. Upon information and belief, Perrigo Israel filed or caused to be filed with the FDA ANDA No. 205397, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

14. Upon information and belief, Perrigo Israel's ANDA No. 205397 seeks FDA approval to sell in the United States Perrigo's generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya®.

15. Dow received a letter from Perrigo Israel dated October 2, 2013, purporting to be a Notice of Certification for ANDA No. 205397 ("Perrigo's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

16. Perrigo's notice letter alleges that Perrigo Israel has submitted to the FDA ANDA No. 205397 seeking FDA approval to sell generic clindamycin phosphate and benzoyl peroxide gel, intended to be a generic version of Acanya®.

17. Upon information and belief, ANDA No. 205397 seeks approval of Perrigo's generic clindamycin phosphate and benzoyl peroxide gel that is the same, or substantially the same, as Acanya®.

18. Under 35 U.S.C. § 271(e)(2), Perrigo Israel has infringed at least one claim of the '434 patent by submitting or causing to be submitted to the FDA ANDA No. 205397 seeking approval for the commercial marketing of Perrigo's generic clindamycin phosphate and benzoyl peroxide gel before the expiration date of the '434 patent.

19. Upon information and belief, Perrigo's generic clindamycin phosphate and benzoyl peroxide gel will, if approved and marketed, infringe at least one claim of the '434 patent.

20. Upon information and belief, Perrigo Israel will, through the manufacture, use import, offer for sale and/or sale of Perrigo's generic clindamycin phosphate and benzoyl

peroxide gel, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '434 patent.

21. Upon information and belief, Perrigo Israel's actions relating to ANDA No. 205397 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Perrigo Company.

WHEREFORE, Plaintiffs Dow and Valeant respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claim set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '434 patent by submitting or causing to be submitted ANDA No. 205397 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Perrigo's generic clindamycin phosphate and benzoyl peroxide gel before the expiration of the '434 patent;
2. order that the effective date of any approval by the FDA of Perrigo's generic clindamycin phosphate and benzoyl peroxide gel be a date that is not earlier than the expiration of the '434 patent, or such later date as the Court may determine;
3. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Perrigo's generic clindamycin phosphate and benzoyl peroxide gel until expiration of the '434 patent, or such later date as the Court may determine;
4. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Perrigo Israel's ANDA No. 205397 until expiration of the '434 patent;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses and disbursements in this action, including reasonable attorneys fees;
6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: November 15, 2013

Respectfully submitted,

s/ John F. Brenner _____
John F. Brenner
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
Suite 400, 301 Carnegie Center
Princeton, NJ 08543-5276
(609) 452-0808
brennerj@pepperlaw.com
Attorneys for Plaintiffs
DOW PHARMACEUTICAL SCIENCES, INC. and
VALEANT PHARMACEUTICALS NORTH
AMERICA LLC

Of Counsel:

Charles E. Lipsey
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
(571) 203-2700

Bryan C. Diner
Justin J. Hasford
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000